

IN THE SPECIFICATION

Please amend numbered paragraphs [0007], [0013], [0017], [0021], [0033], [0035], [0045], [0048], [0051], [0055], [0056], [0075], [0076], [0093], [0099], [00105], [00107], [00111] and [00112], as follows:

[0007] Present practice is to place tubes into the jejunum by endoscopy. Patient sedation is required and gastroenterologists have difficulty pushing the tubes out of the stomach, through the pylorus and then past the Ligament of Trietz Treitz.

[0013] Another object is to provide a tube insertion assembly which allows the use of a small, very flexible 8Fr-8 French (Fr) feeding tube, rather than stiffer 10Fr or-12fr-12Fr tubes.

[0017] Another object is to prevent necrosis in the nasopharynx, pylorus and the Ligament of Trietz Treitz by allowing the use of a small, flexible 8Fr tube.

[0021] The catheter and dual stylet or stylet and guide wire assembly of the present invention can be used for any medical catheter insertion where a stylet or guide wire is conventionally used. One embodiment described in the present application is used for naso-enteral insertion of a feeding tube into and through the stomach, the duodenum and finally into the jejunum. This use presents some unique requirements for adjustable variability of tube stiffness. Moderate stiffness is provided for initial insertion through the nasopharynx, the esophagus and into the stomach. Considerably more stiffness is then provided to transmit pushing force from outside the patient to the catheter tip as it is pushed through the pylorus into the duodenum and to the Ligament of Trietz Treitz. After the stiffened leading end of the catheter tube reaches the Ligament of Trietz Treitz, it is made more flexible so it can navigate around the tight curve formed by the Ligament of Trietz Treitz and into the jejunum.

[0033] 7. under fluorescopy, fluoroscopy, advancing the primary and secondary stylet stiffened catheter into the duodenum to the Ligament of Trietz Treitz;

[0035] 9. under fluorescopy fluoroscopy, advancing the tube tip to its desired final location, beyond the Ligament of Trietz Treitz and in the jejunum;

[0045] 6. under fluoroscopy, advancing the guide wire through the pylorus and the duodenum, past the Ligament of-Trietz Treitz and into the jejunum;

[0048] 9. under fluoroscopy, advancing the catheter tip on the wire, past the Ligament of-Trietz Treitz, into the jejunum; and

[0051] Regardless of whether the aforescribed assemblies and methods incorporate single lumen or multi-lumen tubes with mid-port boluses, or utilize dual stylet or stylet and guide wire combinations, in another alternate form of the invention a normally coiled, single lumen tube section is formed in the tube adjacent the distal end of the tube. This coiled section is then uncoiled, i.e., straightened, by a stylet and/or the guide wire and passed through the stomach, pylorus and duodenum to the Ligament of-Trietz Treitz. The tip of the tube is then moved into the jejunum over the guide wire in this configuration. When the bolus tip of the tube is properly positioned in the jejunum, the guide wire is removed, permitting the section to resume its normally coiled, larger diameter configuration. This configuration enhances the effect of peristalsis in the jejunum on the tube and tip, and retains them more securely in the jejunum.

[0055] FIG. 3 is a sectional view through the connector of FIG. 1 at line 2-2 of FIG. 1 showing the flow-through lumen and the socket for the wire stylet;

[0056] FIG. 4 is a sectional view of the connector of FIG. 1 at line 3-3 of FIG. 2 with a stylet in place;

[0075] FIG. 23 shows both stylets remaining in place for maximum stiffness, the catheter having been pushed through the pylorus and into the duodenum up to the Ligament of-Trietz Treitz;

[0076] FIG. 24 shows the secondary stylet retracted approximately 12 inches, the primary stylet remaining in place, so as to provide reduced but adequate stiffness so that the tube can be pushed around the Ligament of-Trietz Treitz into the jejunum;

[0093] Referring now also to FIGS. 1-14, the catheter tube sub-assembly 12 comprises an 8 Fr French (Fr)-tube 20 having a bolus tip 22 on its distal end. A

conventional Y-connector 24 is mounted on its proximal end. The Y-connector has a conventional inlet port 26 at its proximal end.

[0099] Referring now to FIGS. 21-25, FIG. 21 shows stylet sub-assembly 16 disconnected from stylet sub-assembly 14 and its stylet 40 28-withdrawn approximately 35 inches. In this configuration, the assembly 10 provides a more flexible tube 20 for insertion through a patient's nose.

[00105] There are several ways of inserting the catheter tip 222 into the jejunum according to the invention. With a first, an ultra-slim endoscope is inserted through the nose and advanced through the stomach, into the duodenum, through the pyloric valve. The scope is advanced just proximal to the Ligament of Treitz. The guide wire 214 is then threaded through the scope and fed beyond the scope, around the Ligament of Treitz, into the jejunum. The scope is then carefully removed, leaving the guide wire in place. The catheter assembly with the stylet in place is then fed over the guide wire until the bolus tip 222 comes into proximity with the pyloric valve. The catheter tip 222 has a passage 229 formed in its bullet nose 228 that allows the passage over the guide wire. The stylet connector is then unseated from the catheter Y-connector. The stylet is held in place so that its distal end remains just proximal to the pylorus as the catheter is advanced over the guide wire until the bolus tip 222 is positioned beyond the Ligament of Treitz, in the jejunum. The guide wire is then removed and the catheter is ready for jejunal feeding.

[00107] FIG. 30 shows the catheter assembly 212 in place with its tip bolus 222 next to the pylorus and a single stylet 282 232 in place immediately adjacent the tip bolus. FIG. 31 shows the guide wire 214 threaded through the catheter, into the duodenum and beyond the Ligament of Treitz. FIG. 32 shows the stylet connector disconnected from the catheter tube assembly and the catheter tube advanced over the guide wire 214 into the duodenum, up to a point just before the Ligament of Treitz. In the illustrated method, the distal end of the stylet remains in the stomach. However, the stylet might be advanced through the pylorus into the duodenum to provide additional stiffness to the catheter, as previously discussed.

[00111] The purpose of the coil section 346 is to provide a larger diameter end section on the tube that is, nevertheless, very flexible and resilient. Peristalsis exhibited by the jejunum can then hold the tip bolus 322 more easily. According to the invention, however, the coil section-336 346 is uncoiled, and straightened by the stylet and the guide wire before it is passed from the stomach, through the pyloric valve and into the duodenum. The passage 329 in the nose 328 of the tip bolus 322 for the wire 314 is shown.

[00112] Referring now to FIG. 39, when the guide wire and stylet are removed, with the bolus 322 and the straightened coil section 346 in the jejunum, the unrestricted coil section automatically assumes its helical form. The tube 320 and tip bolus 322 then cannot be inadvertently pulled out past the Ligament of Trietz Treitz.